Decision Memo for Blood Glucose Testing (Revision of ICD -9-CM Codes for Osteomyelitis) (CAG-00183N)

Decision Summary

CMS intends to alter the list of covered diagnoses for blood glucose by deleting the present line that reads: 730.07-730.27, Osteomyelitis of tarsal bones. In its place we intent to add the following ICD-9-CM codes and descriptions:

730.07 Acute osteomyelitis of ankle and foot
730.17 Chronic osteomyelitis of ankle and foot
730.27 Unspecified osteomyelitis of ankle and foot

Pursuant to section 1869(f)(1)(B) of the Social Security Act, the term “national coverage determination” means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title [XVIII], but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.” Thus, the addition of the ICD-9-CM codes to given services will not be subject to review under section 1869(f).

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

To: Administrative File: CAG-00183N Blood Glucose Testing (Revision of ICD-9-CM Codes for Osteomyelitis)

From:

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Acting Director, Division of Items and Devices
Coverage and Analysis Group

Jackie Sheridan-Moore
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Coverage and Analysis Group

Re: Coverage Decision Memorandum for Blood Glucose Testing

Date: May 15, 2003

This memorandum serves the purpose of addressing a request for correcting a mismatch between the osteomyelitis ICD -9-CM codes covered and the description of those codes in the blood glucose testing national coverage determination (NCD). As discussed below, it has always been our intent that the ICD-9-CM codes reflect the narrative indications for the test in the NCD.

Background

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. One of these NCDs was for blood glucose testing. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the blood glucose testing NCD, CMS determined that coverage of specific blood glucose tests was reasonable and necessary for certain medical indications. The NCD contains a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM codes covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM codes denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM codes that do not support medical necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the NCD that any ICD-9-CM code not listed in either of the ICD-9-CM sections would be categorized into group three.

History of Medicare Coverage

Since one of the goals of the negotiated rulemaking was to promote national uniformity, CMS hired a contractor to develop software that could be used by the Medicare claims processors so that we could ensure that all of the contractors were implementing the NCDs identically. As part of its review of the NCDs, the contractor noted a mismatch between the series of IDC-9-CM codes and its description. Specifically, we noted a mismatch between the listed codes and the code description of osteomyelitis in the blood glucose NCD. The NCD includes the coding range 730.07-730.27 and the description “osteomyelitis of tarsal bones.” The fifth digit of the codes in this range indicates location of the osteomyelitis and the codes listed include unspecified, shoulder, upper arm, forearm, hand, pelvic region and thigh, lower leg, ankle and foot, other sites and multiple sites.

We posted an announcement on our coverage website on February 21, 2003 announcing our intent to analyze the issue of changing the codes for osteomyelitis included in the blood glucose NCD to 730.07, acute osteomyelitis of the ankle and foot, 730.17, chronic osteomyelitis of the ankle and foot, and 730.27, unspecified osteomyelitis of the ankle and foot.

We invited public comment through March 21, 2003. We received one comment from Bruce Cohen, MD. Dr. Cohen stated:

“Primarily ulcers and subsequent infection/osteomyelitis affect the bones of the forefoot, midfoot, hindfoot and ankle. Oftentimes the infection is concomitant to Charcot arthropataic changes that cause significant destruction of the tarsals as well as the ankle. I would make sure that the applicable codes include: tibia, fibula, tarsals, metatarsals, phalanges.”

Dr. Cohen did not provide a rationale for or evidence in support of inclusion of sites other than the foot and ankle.

CMS Analysis

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we clearly stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. In Program Memorandum AB 02-110 we stated our intent as follows:

“The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, requests for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD. Clerical maintenance of the coding lists will be made without following the NCD process. Clerical maintenance may include such actions as revision of codes to be consistent with the annual CPT and ICD-9-CM coding updates, expansion of codes to full range of digits, and correction of code errors that may exist.”

The blood glucose testing NCD includes the following in the list of covered indications:

“In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause.”

The narrative of the NCD includes chronic or recurrent infections, local skin infections, and ulceration but does not address location. However, the intent of the NCD was to limit the covered indication of osteomyelitis to infection involving the foot and ankle. This determination is reflected in the choice of descriptor (“osteomyelitis of tarsal bones”) assigned to the list of applicable codes. Thus, we believe it is appropriate to only include the codes for acute, chronic and unspecified osteomyelitis of the foot and ankle in the list of covered diagnosis codes for blood glucose testing.

As noted above, Dr. Bruce Cohen commented suggesting the addition of tibia, fibula, and phalanges to the list of covered diagnosis for blood glucose. Dr. Cohen did not provide any information in support of his suggestion. Nonetheless, we conducted a literature search in PubMed using the terms osteomyelitis, diabetes mellitus and each of the bones in question. The search produced no matches on phalanges, two matches for fibula and 7 matches for tibia. These articles addressed evaluation and treatment methodologies. They did not support osteomyelitis of the tibia, fibula, or phalanges as a common complication or comorbidity of diabetic patients or the medical necessity of blood glucose testing for these conditions. However, we would reconsider this determination if presented with new evidence.

Decision

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